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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,842	08/29/2003	Bret A. Ferree	BAF-16402/29	2836
7590	01/10/2005			EXAMINER
John G. Posa Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C. 280 N. Old Woodward Ave., Suite 400 Birmingham, MI 48009-5394			JACKSON, SUZETTE JAMIE	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 01/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,842	FERREE, BRET A.	
	Examiner Suzette J Gherbi	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 October 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 8/29/03 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

1. Applicant's amendment dated October 18, 2004 has been received in application serial number 10/652,842.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not recite "locating a component of the ADR within an intervertebral disc space in spaced apart relation".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rogozinski 5,888,226. Rogozinski discloses the invention as claimed comprising: A

method of fixing an artificial disc replacement (10) to a vertebral disc endplate by locating a component of an artificial disc replacement (ADR) *within an intervertebral disc space* in spaced-apart relation to the vertebral endplate; and introducing cement between the component and the vertebral endplate (see col. 5, lines 14-15). (see col. 3, lines 47-53).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7, 10-11, 14-15, and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogozinski in view of Johnson 6,595,998. Rogozinski has been disclosed above however Rogozinski does not specify the cement properties. Johnson teaches that cement can contain an antibiotic (col. 9, line 57); forming a receiving hole or cavity in the vertebral body; wherein the ADR comprises a rim (266) wherein cement is injected under fluoroscopic observation (col. 22, line 49). The steps of forming a passage through the vertebra having the endplate to inject the cement are inherent. It would have been obvious to one having ordinary skill in the art to incorporate these

properties because utilizing an antibiotic would further help the prosthesis from be rejected from the body and the fluoroscopy would assist the surgeon in correct placement and monitoring of the device.

7. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rogozinski in view of Gould et al. 2004/0067876. Rogozinski has been disclosed above however they do not mention a hypotensive anesthesia prior to fixing the ADR. Gould et al. teaches the use of hypotensive anesthesia.[0009]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize this type of anesthesia prior to fixing an ADR because it would help control any patient that may suffer large amounts of blood loss.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over in Rogozinski view of Trieu 2004/0133280. Rogozinski has been disclosed above however Rogozinski does not specify the use of a hemostatic agent prior to fixing the ADR. Trieu teaches ADR replacements that utilize cement and Hemostatic agents [0085]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of a Rogozinski and utilize haemostatic agents in order to arrest any hemorrhaging that may occur.

9. Claims 12, 17-19 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogozinski view of Carbone 5,340,362. Rogozinski has been

disclosed above however and while Johnson et al. does mention that the introduction of cement between the component and the vertebral endplate utilize a separate tool that is removed before the endplate is placed in a spaced-apart relation to the vertebral endplate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize separate tools for different stages of filling the cavity and ADR with cement because a tool for inserting cement may be *structurally* different (i.e. a cannula nozzle) than the tool for inserting an ADR (i.e. a tool with mating structure of the ADR).

Response to Arguments

10. Applicant's arguments filed 10/18/04 have been fully considered but they are not persuasive. Applicant has amended the claims to state that the ADR device is within an intervertebral disc space. The new office rejection above addresses these claims as currently written. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case,

the combination is proper because Rogozinski uses an ADR within a disc space and cement but does not give specifics about the cement delivery while the other teaching references give more detailed specifics about biocompatible cement, its deployment and its uses in the spinal region.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lawson 6,146,422 teaches an ADR that utilizes cement and Erickson et al. 6,368,350 also teaches an ADR that utilizes cement.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3738

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

15. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J-J Gherbi

28 December 2004


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700